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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Andre Stamm

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

08/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,522	Applicant(s) STAMM ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,13,14,16,18-20,25-33,36,38,39 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,13,14,25-33,38,39 and 46-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,18-20,36 and 41-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/08; 6/19/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election Requirement filed 04/30/09, the Response and Amendment to Non-Final Office Action filed 07/23/08 and the Information Disclosure Statements (IDS) filed 07/23/08 and 06/19/09 is acknowledged.

Applicant's election of Species (b) Cmax in the reply filed on 04/30/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 46-48 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/30/09.

Claims 6, 7, 13, 14, 16, 18-20, 25-33, 36, 38-39 and 41-48 are pending in this action. Claim 16 has been amended. New claims 41-48 have been added. Claims 6, 7, 13, 14, 25-33, 38 and 39 remain withdrawn from consideration (based on non-elected invention - see Response to Restriction filed 09/06/06). Claims 46-48 are withdrawn herein. Claims 1-5, 8-12, 15, 17, 21-24, 34, 35, 37 and 40 have previously been cancelled. Claims 16, 18-20, 36 and 41-45 remain rejected.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 07/23/09 and 06/19/09 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

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* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 42 contain the trademark/trade name "*Lipanthyl®200M*". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a fenofibrate formulation and, accordingly, the identification/description is indefinite.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 18-20, 36 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause (U.S. Pat. No. 4,859,703) in view of Deboeck *et al.* (hereinafter “Deboeck”) (U.S. Pat. No. 5, 545,628).

Krause ('703) teaches single dose formulations containing a combination of a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate or *fenofibrate* and an ACAT inhibiting agent that are effective pharmaceutical formulations for regulating blood serum lipid and cholesterol levels (see Abstract); (col. 2, lines 12-22); (col. 4, lines 15-19).

Oral administration forms taught include tablets, as well as capsules, powders and sachets (col. 5, lines 12-20). Powders and tablets contain between about 5 to about 70% by weight of the active ingredient.

The pharmaceutical preparations can be in unit dosage forms (col. 5, lines 36-44).

In therapeutic use, as hypolipidemic or hypcholesterolemic agents, the pharmaceutical compositions are administered to the patient at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, which can be selected from among others, fenofibrate (col. 5, lines 45-58).

Examples 5-10 at columns 7-9 demonstrate various immediate release tablet formulations comprising a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Example 5, for instance presents an immediate release tablet formulation containing 300 mg of lipid regulating agent chosen from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Similarly, Example 6 demonstrates an immediate release tablet formulation containing 450 mg of lipid regulating agent.

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Krause teaches that the pharmaceutical compositions are administered at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, such as for instance, fenofibrate (col. 5, lines 45-58).

Krause does not teach fenofibrate to be provided in a daily dose lower than 200 mg.

Deboeck *et al.* ('628) teach a pharmaceutical composition provided for treating hyperlipidemia or hypercholesterolemia or both, which contains an effective amount of fenofibrate and an excipient (see Abstract); (col. 1, line 6 - col. 2, line 67).

Deboeck teaches that generally, the effective daily amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (col. 8, lines 18-24); and Claim 12. Also see col. 4, lines 51-63 and col. 7, lines 57-67. This amount/range meets Applicants claimed amount of a daily dose of lower than 200 mg as recited in instant claim 16. These amounts are used to advantageously treat hyperlipidemia or hypercholesterolemia (col. 8, lines 18-20).

Deboeck also teaches that the compositions contain from about 5% to 95% by weight of fenofibrate (col. 3, lines 49-58). Moreover, with regards to amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a fenofibrate formulation that comprises a daily effective amount of fenofibrate in amounts lower than 200 mg, such as about 100 mg as taught by Deboeck within the lipid formulations of Krause. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Deboeck explicitly teaches fenofibrate pharmaceutical compositions whereby the daily effective amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day and Deboeck teaches that these amounts are used in order to advantageously and effectively treat hyperlipidemia or hypercholesterolemia. The expected result would be an improved fenofibrate formulation that has increased bioavailability for the beneficial treatment of hyperlipidemic and high cholesterol conditions.

Regarding the claim 16 and 42 limitations of “bioavailability being greater than that of Lipanthyl®200M” this limitation does not impart patentability to the present claims. Example 3 on page 12 of the specification indicates that the enhanced bioavailability occurs as a result of the specific bioavailability parameters (AUC, C_{max}, T_{max}). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC, C_{max}, T_{max} levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, the limitation does not define over the prior art disclosure. The instant claims are generic in scope as compared to that with the particular examples (i.e., Example 3) of the specification.

Regarding claims 41-45, which recite a fenofibrate tablet wherein the ‘bioavailability is assessed by AUC, C_{max} or both’, it is the position of the Examiner that

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this limitation is met by the combination teachings of the prior art. The prior art explicitly teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38. The art further teaches bioavailability parameters (AUC, C_{max}, T_{max}) and teaches suitable bioavailability levels (see Table 4 of Deboeck at column 8). The manner by which the bioavailability of fenofibrate is assessed does not impart patentability to the claims since the art clearly recognizes fenofibrate formulations that exhibit increased or improved bioavailability. Moreover, a product is being claimed herein and not a method of assessing bioavailability of an active ingredient. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved or assessed. Furthermore, Applicant credits the improved bioavailability of their composition based on their fenofibrate *processing* techniques. It is noted that the instant claims are drawn to a product and not a process of manufacturing fenofibrate. In any event, the prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosage of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

* * * * *

Claims 16, 18-20, 36 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghebre-Sellassie *et al.* (hereinafter “Ghebre-Sellassie”) (U.S. Pat. No. 4,927,639) in view of Krause (U.S. Pat. No. 4,859,703) and further in view of Deboeck *et al.* (hereinafter “Deboeck”) (U.S. Pat. No. 5, 545,628).

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Ghebre-Sellassie *et al.* ('639) teach a disintegratable formulation of gemfibrozil providing both immediate and sustained release and comprises a tablet compressed from a mixture of a first and second granulation and a disintegration excipient (see Abstract); (col. 1, lines 9-15; 60-68); (col. 2, lines 63-64).

Ghebre-Sellassie teaches gemfibrozil, a widely used antihyperlipoproteinemic agent (col. 1, lines 9-15).

Ghebre-Sellassie does not teach fenofibrate.

Krause ('703) teaches single dose formulations containing a combination of a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate or *fenofibrate* and an ACAT inhibiting agent that are effective pharmaceutical formulations for regulating blood serum lipid and cholesterol levels (see Abstract); (col. 2, lines 12-22); (col. 4, lines 15-19).

Oral administration forms taught include tablets, as well as capsules, powders and sachets (col. 5, lines 12-20). Powders and tablets contain between about 5 to about 70% by weight of the active ingredient.

The pharmaceutical preparations can be in unit dosage forms (col. 5, lines 36-44).

In therapeutic use, as hypolipidemic or hypcholesterolemic agents, the pharmaceutical compositions are administered to the patient at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, which can be selected from among others, fenofibrate (col. 5, lines 45-58).

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Examples 5-10 at columns 7-9 demonstrate various immediate release tablet formulations comprising a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Example 5, for instance presents an immediate release tablet formulation containing 300 mg of lipid regulating agent chosen from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Similarly, Example 6 demonstrates an immediate release tablet formulation containing 450 mg of lipid regulating agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate any lipid regulating agent, particularly fenofibrate, as taught by Krause within the lipid composition of Ghebre-Sellassie. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Krause explicitly teaches single dose formulations containing a combination of a lipid regulating agent that can be selected from gemfibrozil, clofibrate, bezafibrate or *fenofibrate* and teach that such lipidemic agents are effective for regulating blood serum lipid and cholesterol levels. The expected result would be an enhanced fenofibrate composition that exhibits increased bioavailability and effective treatment of hyperlipidemia and hypercholesterolemia.

The teachings of Ghebre-Sellassie and Krause are delineated above. They do not teach fenofibrate to be provided in a daily dose lower than 200 mg.

Deboeck *et al.* ('628) teach a pharmaceutical composition provided for treating hyperlipidemia or hypercholesterolemia or both, which contains an effective amount of fenofibrate and an excipient (see Abstract); (col. 1, line 6 - col. 2, line 67).

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Deboeck teaches that generally, the effective daily amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (col. 8, lines 18-24); and Claim 12. Also see col. 4, lines 51-63 and col. 7, lines 57-67. This amount/range meets Applicants claimed amount of a daily dose of lower than 200 mg as recited in instant claim 16. These amounts are used to advantageously treat hyperlipidemia or hypercholesterolemia (col. 8, lines 18-20).

Deboeck also teaches that the compositions contain from about 5% to 95% by weight of fenofibrate (col. 3, lines 49-58). Moreover, with regards to amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a fenofibrate formulation that comprises a daily effective amount of fenofibrate in amounts lower than 200 mg, such as about 100 mg as taught by Deboeck within the lipid formulations of Ghebre-Sellassie and alternatively, Krause. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Deboeck explicitly teaches fenofibrate pharmaceutical compositions whereby the daily effective amount of fenofibrate for humans ranges from

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about 100 mg to 600 mg per day and Deboeck teaches that these amounts are used in order to advantageously and effectively treat hyperlipidemia or hypercholesterolemia. The expected result would be an improved fenofibrate formulation that has increased bioavailability for the beneficial treatment of hyperlipidemic and high cholesterol diseases.

Regarding the claim 16 and 42 limitations of “bioavailability being greater than that of Lipanthyl®200M” this limitation does not impart patentability to the present claims. Example 3 on page 12 of the specification indicates that the enhanced bioavailability occurs as a result of the specific bioavailability parameters (AUC, C_{max}, T_{max}). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC, C_{max}, T_{max} levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, the limitation does not define over the prior art disclosure. The instant claims are generic in scope as compared to that with the particular examples (i.e., Example 3) of the specification.

Regarding claims 41-45, which recite a fenofibrate tablet wherein the ‘bioavailability is assessed by AUC, C_{max} or both’, it is the position of the Examiner that this limitation is met by the combination teachings of the prior art. The prior art explicitly teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38. The art further teaches bioavailability parameters (AUC, C_{max}, T_{max}) and teaches suitable bioavailability levels (see Table 4 of Deboeck at column 8). The manner by which the bioavailability of fenofibrate is assessed does not impart patentability to the

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claims since the art clearly recognizes fenofibrate formulations that exhibit increased or improved bioavailability. Moreover, a product is being claimed herein and not a method of assessing bioavailability of an active ingredient. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved or assessed. Furthermore, Applicant credits the improved bioavailability of their composition based on their fenofibrate *processing* techniques. It is noted that the instant claims are drawn to a product and not a process of manufacturing fenofibrate. In any event, the prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosage of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

* * * * *

Response to Arguments

Applicant's arguments filed 23 July 2008 have been fully considered but they are not persuasive.

Applicant argues that their “improved bioavailability of their composition is based on a novel process” or their fenofibrate processing techniques. Namely, Applicant argues that their fluid-bed granulation techniques attribute to enhanced bioavailability of the formulation. This argument was not deemed persuasive. The instant claims are drawn to a fenofibrate product and not a process of manufacturing fenofibrate. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved (such as by specific manufacturing processes – i.e., fluid bed granulation). Thus, Applicant's arguments drawn to the advantages of the manufacturing process are not commensurate in scope with the instant product claims. In any event, the

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prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosage of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

- **Rejection under 35 U.S.C. §103(a) over Krause (US‘703) and Deboeck (US ‘628); and Ghebre-Sellassie (US ‘639) in view of Krause and Deboeck:**

Applicant argues, “Krause compositions may comprise from 300 to 1200 mg of fenofibrate. Krause tablets should be bioequivalent to Lipanthyl®300, the first generation of fenofibrate drugs. Krause tablets are not bioequivalent to Lipanthyl®200M, let alone superior to them.”

This argument was not found persuasive. While it is noted that the Krause compositions may comprise from 300 to 1200 mg of fenofibrate, and not a daily dose of ‘lower than 200 mg’, the secondary reference of Deboeck was relied upon for the teaching of fenofibrate compositions whereby the fenofibrate ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (see col. 8, lines 18-24). Deboeck further teaches that their pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38). Thus, Deboeck amply demonstrates using lower dosages of fenofibrate to obtain therapeutic and beneficial results, such as enhanced bioavailability. There is no patentability seen in Applicant’s limitation of “wherein the bioavailability is greater than that of Lipanthyl®200M”, since the prior art vividly teaches fenofibrate compositions having improved bioavailability; the same objective as that desired by Applicant.

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Regarding the rejection of Ghebre-Sellassie (US '639) in view of Krause and Deboeck, Applicant argued, "Ghebre-Sellassie is directed to gemfibrozil, where the tablet has both an immediate release part and a sustained release part in it, obtained by two different granulations". Applicant's arguments have been considered but were not found persuasive. Admittedly, while Ghebre-Sellassie is directed to gemfibrozil, the secondary reference of Krause was relied upon for the teaching of compositions comprising fenofibrate or alternatively gemfibrozil. The argument that Ghebre-Sellassie's tablet has both an immediate release part and a sustained release part in it was not convincing, since the instant claims do not exclude the sustained release portion of Ghebre-Sellassie. The instant claims permit the controlled release portion of the prior art.

Regarding Deboeck, Applicant argued, "Deboeck is directed to fenofibrate composition, specifically to a generic of Lipanthyl®200M". Thus, Deboeck discloses a composition having the same bioavailability as Lipanthyl®200M". Deboeck is directed to capsules and not to a tablet."

These arguments were not deemed persuasive. Deboeck explicitly teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38. The art further teaches bioavailability parameters (AUC, C_{max}, T_{max}) and teaches suitable bioavailability levels as that instantly desired by Applicant (see Table 4 of Deboeck at column 8). It is noted that Deboeck is drawn to fenofibrate capsules and not tablets. However, the primary reference of Krause initially recognizes and teaches various forms of fenofibrate formulations, including both capsules and tablets. See col. 5, lines 12-20

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of Krause. Thus, the art is aware of the array of dosage forms available, particularly tablets.

Lastly, Applicant argued, “The invention is directed to a composition which has a bioavailability that is greater than that of Lipanthyl®200M. Krause and Ghebre-Sellassie provide tablets having a bioavailability that is lesser than that of Lipanthyl®200M. Deboeck provides capsules having the same bioavailability as Lipanthyl®200M. Thus, none of the documents, either individually or in combination render the instant invention obvious.”

Applicant’s arguments were not held persuasive. Applicant attributes improved bioavailability of their composition based on their process of manufacturing fenofibrate and directs the Examiner to Table 3 of the specification and Figure 1. The argument of improved bioavailability over that of Lipanthyl®200M was not convincing since the claims are generic in scope as compared to that with the particular examples of the specification. The enhanced bioavailability particularly of Example 3 on page 12 occurs as a result of the specific bioavailability parameters (AUC, C_{max}, T_{max}). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC, C_{max}, T_{max} levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, in response to applicant's argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., improved bioavailability as a result of the specific AUC, C_{max}, T_{max}) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

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See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The art in combination achieves fenofibrate formulations having increased bioavailability, which is the same objective sought herein by Applicant. For these reasons, Applicant's arguments remain unpersuasive.

The 103(a) rejections of record have been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 6, 7, 13, 14, 25-33 and 38-39 drawn to an invention nonelected with traverse in the reply filed on 06 September 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

August 12, 2009

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